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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,327	09/28/1999	GEORGE H. LOWELL	406462000102	2613

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	18

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/407,327	Lowell
Examiner	**Art Unit**
Jennifer Graser	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Request for CPA & Declaration, 9/11/01* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4 and 6-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4 and 6-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on September 11, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/407,327 is acceptable and a CPA has been established. The After Final Amendment previously submitted July 13, 2001, Paper No.12/B has been entered. Additionally, the copy of the 1.132 Declaration by George Lowell from parent file 08/677,302 has been acknowledged and entered into record. The Terminal Disclaimer filed 7/16/01 has effectively overcome the former Obviousness-type double patenting rejection.

An action on the CPA follows.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the continuing data information provided on the corrected filing receipt and the information contained on page 2 of amendment 7/A submitted by Applicants on 6/13/2000 is INCORRECT. The application mentioned, 08/673,756, PAT 5,858,268 is **NOT** an application filed by Applicant. This appears to be a typographical mistake on Applicant's part. The correct application number should be 08/637,756, PAT 5,961,970.

Applicants must submit a new request for a Corrected filing receipt and correct the insertion on the first line of the specification which contains the priority information. Additionally, a substitute oath/declaration is required. See below.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The oath/declaration claims priority to an application by another. The application in the claim for priority on page 2 of the oath/declaration, 08/673,756 is **NOT** an application filed by Applicant. Applicant cannot claim priority to someone else's application. This appears to be a typographical mistake on Applicant's part. The correct application number appears as it should be 08/637,756. A substitute oath/declaration is required.

Claim Rejections - 35 USC § 112

4. Claims 1-4 and 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and 6 are vague and indefinite because it is unclear what is encompassed by a "glycolipid". The specification defines 'glycolipid' as 'a ganglioside or a variety of protein or peptides with hydrophobic anchors'. This definition is extremely broad and is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the

specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed when they are drawn to a "glycolipid". A specific definition of a 'glycolipid' is not provided in the specification. A 'variety of proteins which natural of engineered hydrophobic anchors' is an unduly broad definition that does not allow for one to understand the metes and bounds of the invention.

In claim 4 the word "derived" should be changed to "isolated". The term "derived" does not provide the character or properties from the source that are to be retained in the final product, e.g., paper is derived from wood but is very different from wood.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide and methods of achieving immunity using these vaccines/compositions, does not reasonably provide enablement for vaccines or immunogenic compositions comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one glycolipid and a pharmaceutically acceptable carrier, nor does it

enable methods of achieving immunity using these vaccines/compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. .

The specification has successfully demonstrated that immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide when administered can impart or achieve immunity to neisserial, gonococcal and meningococcal infections, etc.. However, the specification is silent as to which glycolipids could be used in a hydrophobic complex to with proteosomes to achieve or impart this same type of immunity. The specification defines 'glycolipid' as 'a ganglioside or a variety of protein or peptides with hydrophobic anchors'. This definition is extremely broad and reads on millions of small peptides, large peptides, proteins and gangliosides. The vaccine art is highly unpredictable. Applicants have not enabled this scope of invention. There are no challenge experiments provided which demonstrate the use of even a single glycolipid and a proteosome. Further, the definition of glycolipid provided by the specification is so broad, it is unclear that an example using one specific glycolipid would enable another, i.e., a glycolipid of 8 amino acids in length may behave very different from one 200 amino acids in length. The specification has only enabled immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide. Applicants have shown that detoxified LPS was ineffective when compared

to the use of non-detoxified LPS which demonstrates the unpredictability with vaccines even when using the same components in different forms.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. In Re Wands, 8 USPQ2d 1400.

The instant specification does not enable the broad scope of the invention. 1) The nature of the invention is a vaccine or immunogenic composition comprising proteosomes and at least one non-detoxified lipopolysaccharide or a glycolipid and a pharmaceutically acceptable carrier and methods of achieving immunity through the administration of these vaccines/immunogenic compositions. 2) The state of the prior art at the time the invention was made taught that compositions comprising proteosmoes and detoxified lipopolysaccharides were effective immunogens. However, the state of the prior art was silent as to the effectiveness of proteosomes and a glycolipid which is 'a ganglioside or a variety of protein or peptides with hydrophobic anchors' for achieving immunity. 3) Predictability- If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot

readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is a lack of predictability in the art. The vaccine art is highly unpredictable. This definition of glycolipid is extremely broad and reads on millions of small peptides, large peptides, proteins and gangliosides. Applicants have shown that detoxified LPS was ineffective as a vaccine when compared to the use of non-detoxified LPS which demonstrates the unpredictability with vaccines even when using the same components in different forms. The use of an entirely different compound would lead to an even greater degree of unpredictability. 4) The amount of guidance or direction present needed to enable the invention is inversely related to the amount of knowledge in the state of the prior art. Since little is known in the prior art regarding the use of any glycolipid and protesomes in achieving immunity, the specification as filed is not adequate to support the broad scope of the claimed invention. 5), 6) and 7)- Although the level of skill in the art is high, the breadth of the claims is broad and as stated above the art is unpredictable concerning the likelihood of identifying an effective vaccine comprising any glycolipid and a proteosome.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

J Graser 11/20/01

Jennifer Graser
Primary Examiner
Art Unit 1645